

**REMARKS**

In order to emphasize the patentable distinctions of applicants' invention over the prior art of record, claims 14 and 22 have been amended to incorporate subject matter previously delineated by claims 25 and 23, respectively dependent thereon. Amended claim 14 further includes the features of intervening claim 24. The subject matter of claims 2, 3, 4, 5, 6, and 8 is now presented collectively as new claim 26. For the sake of clarity, claims 9 and 12 have been amended to depend from claim 26 instead of claim 8. Claims 1-8, 10, 15-16, 18-19, and 25 have been cancelled to expedite prosecution of this application. Claims 20-21 were previously cancelled and claims 10 and 17 were withdrawn from consideration as being directed to non-elected species.

Applicants' invention, as delineated by remaining claims 9, 11-14, 22, 24, and 26, as amended, is directed to a surgical implement detection system for detecting surgical implements within a wound at the conclusion of a surgical procedure. Compared to previously-known markers for article detection systems, the present inventive marker has a significantly reduced size. As a result, the marker is readily attached or similarly associated with surgical implements, including both reusable surgical tools, disposable items such as surgical sponges, or other like articles. The marker has a plurality of magnetostrictive amorphous metal strips disposed in a cavity with their orientation being non-parallel. The multiple directions greatly enhance the sensitivity of the marker to interrogating fields having different directions, thereby markedly increasing, if not assuring, the detection of the marker and a surgical implement associated therewith while the implement is still located within a patient's body during surgery. The marker's smaller size permits it to be attached

to items that otherwise could not be protected. In some cases, a surgical item is simply too small to accommodate a conventional marker. The item may be smaller than the typical 1.5" length of a marker operative at about 60 kHz, or it may have no suitable location large enough for such a marker to be placed on it. In other instances, a conventional marker accompanying an item or attached to it would be an impediment to the item's ordinary use, e.g. by interfering with a surgeon's manipulation of the item. Applicants maintain that the prior art has failed to recognize the potential for a smaller, more widely applicable marker that could avoid these detriments.

The problem of implements left behind after the completion of surgical procedures remains a serious and vexing medical issue, because if undetected, these items are highly likely to cause serious, and possibly fatal, injury to a patient. The present system provides a procedure whereby these items can be reliably, quickly, and efficiently detected in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required.

The Examiner has rejected claims 1-5, 14-16, 18, 19, and 22 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over US Patent No. 5,057,095 to Fabian, which discloses a surgical implement detector utilizing a resonant marker. In one embodiment, the Fabian marker is magnetomechanical.

Inasmuch as claims 1-5, 15-16, 18, and 19 have been cancelled, this rejection will be discussed with respect to remaining claims 14, 22, and 26, as now amended.

It is respectfully submitted that Fabian does not disclose or suggest any marker employing a plurality of non-parallel magnetostrictive amorphous metal strips, as required by claims 14, 22, and 26, as amended. Accordingly, applicants maintain that claims 14, 22, and 26 cannot be regarded as anticipated by Fabian. In addition, the multiple, non-parallel strip feature is not suggested by Fabian, precluding any obviousness rejection.

Applicants further maintain that Fabian does not disclose or suggest any marker having a resonant frequency ranging from about 70 to 300 kHz, as also required by all of claims 14, 22, and 26, further predicated patentability of these claims over Fabian.

As set forth at page 8, line 19 to page 9, line 3; page 18, lines 1-15; and page 18, line 23 to page 19, line 10, a marker constructed to operate within such a frequency range advantageously is smaller in size than conventional magnetomechanical markers used in connection with a surgical implement, such as that disclosed by Fabian, but nevertheless has an adequate volume of magnetic material to emit a signal that is large enough to permit highly reliable, rapid detection of the marker in the adverse environment of surgery. There is nothing in Fabian et al. to suggest such a reconstruction. Clearly, speed and reliability of detection are of paramount importance in such a situation. On the other hand, increasing the operating frequency of the detection system necessarily decreases the length of the resonant element of the marker. In addition, reducing the length also typically necessitates decreasing the width of the element in order to maintain a comparable demagnetizing factor. The decrease in total element volume in turn inherently reduces the marker's signal output. The prior art has thus eschewed shorter, higher frequency markers, regarding them as providing inadequate output to permit reliable marker detection. On the other hand, applicants' marker is capable of providing sufficient output as a result of the particular configuration taught.

Advantageously, the compact size of the present marker permits surgical items to be tagged that would be physically impossible to tag using larger conventional markers. As set forth above, many surgical items either do not have a suitable location on which to situate a conventional marker, or the use of the item would be adversely impacted by the presence of the marker. On the other hand, the smaller markers provided by applicants can be used beneficially in such situations. The non-parallel orientation of the strips in the marker further enhance the probability that the marker will, in fact, be detected during its appointed use during surgery.

With respect to previous claims 1, 12, and 13, the Examiner has indicated that Fabian teaches a system for detecting surgical implements using a magnetomechanical marker having a resonant frequency. The range of operation of the system is said to be below about 1 GHz. It is further indicated that the operation of the Fabian system may rely on any of three types of resonance, viz. magnetomechanical, electromechanical, and electromagnetic.

It is axiomatic that a novelty rejection is proper only if every feature of the claims is disclosed in a single reference. The Examiner has acknowledged that Fabian et al. fails to expressly disclose applicants' claimed frequency ranges, admitting that the only guidance provided by Fabian et al. the system operates at a "conventional" frequency. Accordingly, the Examiner has pointed to disclosure by Von Hoene et al. of a magnetomechanically resonant element said to have a resonant frequency of 120.21 kHz, which is alleged to support a position that the "conventional system" disclosed by Fabian employs a resonant frequency of 120.21 kHz.

Applicants respectfully continue to maintain that Von Hoene et al. cannot properly be used in the manner that Examiner has delineated, specifically traversing the propriety of using the later-filed Von Hoene et al. reference to establish any frequency range as being

what Fabian et al. meant by the term “conventional.” In particular, it is submitted that the citation of Von Hoene et al. does not satisfy any of the three narrow situations set forth in MPEP 2131.01 in which multiple references are properly employed in a rejection under 35 USC 102.

Applicants’ 70 to 300 kHz range is clearly not disclosed by Fabian, nor can Von Hoene et al. be regarded as pertinent. Applicants accordingly maintain that the disclosure of the 70-300 kHz is not made with sufficient specificity in Fabian to satisfy the test under *Ex parte Cole*, 2001 WL 1918535 (BPAI, 2001), quoting *Ex parte Lee*, 31 USPQ2d 1105, 1107 (BPAI, 1993). [“Where, as here, a reference describes a class of compositions, the reference must be analyzed to determine whether it describes a composition(s) with sufficient specificity to constitute an anticipation under the statute. *Ex parte Lee*, supra, at 1106-1107, emphasis added, citing *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).]

Moreover, applicants submit that nothing in Fabian would lead a skilled artisan to the particular frequency range required by applicants’ claims. Such a range surprisingly and unexpectedly permits the present magnetomechanical technology to be extended to a far wider range of surgical implements than would be possible using the much larger prior-art tags needed for operation at conventional magnetomechanical frequencies. Such lack of disclosure even further rebuts any purported conclusion that Fabian provides the requisite level of specificity of disclosure. [“If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with ‘sufficient specificity’ to constitute an anticipation of the claims. The unexpected results may also render the claims unobvious.” MPEP 2131.03 (II).]

Applicants thus maintain that Fabian fails to disclose or suggest every feature delineated by amended claims 14, 22, and 26.

In view of the foregoing remarks, it is submitted that the system of claims 1-5, the method of claims 14-16 and 18-19, and the surgical implement of claim 22 are novel and unobvious over Fabian.

Accordingly, reconsideration of the rejection of claims 1-5, 14-16, 18-19, and 22 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Fabian is respectfully requested.

Claims 1-5, 12-16, 18, 19, and 22 were rejected under 35 USC 103(a) as being unpatentable over Fabian in view of US Patent No. 5,338,373 to Von Hoene et al.

Inasmuch as claims 1-5, 15-16, 18, and 19 have been cancelled, this rejection will be discussed with respect to remaining claims 14, 22, and 26, as now amended.

Applicants respectfully submit that Von Hoene et al. fails to disclose or suggest any marker configuration that involves a magnetostrictive element having multiple, non-parallel resonant strips of amorphous metal. Accordingly, Von Hoene et al. does not cure the deficiency of Fabian, as set forth hereinabove in connection with the rejection of claims 1-5, 14-16, 18, 19, and 22 over Fabian et al.

Furthermore, the Von Hoene et al. reference is directed to a method of encoding and decoding a glassy alloy strip to be used as an identification marker. Attention is further drawn to the disclosure at col. 4, lines 18-24, in which the patentees state that "The fundamental aspect of this invention is that the modification to the alloy strip be of such a nature as to change the effective length of the marker. The effective length of an alloy strip

may be calculated for a modified strip by using the physical length and resonant frequency of an unmodified strip having the same composition.”

As noted hereinabove in connection with the rejection over Fabian, the Examiner has acknowledged that Fabian’s disclosure does not provide numerical values of the frequency of the magnetomechanical markers, beyond the generic disclosure of “below 1 gigahertz” and the statement that the resonant frequency is one used by a conventional system. As further set forth hereinabove, nothing in the record establishes that Fabian contemplated any operation of a conventional magnetomechanical system at a frequency in the claimed 70-300 kHz range, let alone a preferred system operating in the ranges 110-250 kHz or 120-200 kHz. While Von Hoene et al. admittedly discloses in Table I a magnetomechanically resonant strip having a resonant frequency of 120.21 kHz, it is submitted that such disclosure falls short of rendering obvious the use of such a strip in a marker appointed for an EAS system, let alone a marker attached to a surgical instrument so as to render such instrument detectable in the manner provided by applicants’ invention. The object of the Von Hoene et al. invention, to the contrary, is to provide a large plurality of unique and measurably discernable markers (see, e.g., col. 2, lines 46-59), wherein the resonant frequency is determined by the effective length of a marker element, not the actual length. Nothing in Von Hoene et al. contemplates or suggests the use of any marker having a 120.21 kHz resonant frequency, let alone such a marker in a medical or surgical context. To the contrary, the various techniques for modifying the effective length of marker disclosed by Von Hoene et al. were all implemented using markers having a resonant frequency of about 55-69 kHz, as provided in Examples 2-7. The Examiner has suggested that Von Hoene et al. teaches changing the length of the marker. However, he has relied on a passage that relates

to changes in effective length resulting from particular processing and not from changes in the actual length of the marker element.

By way of contrast, the present invention provides a marker attachable to a surgical instrument, the marker being of significantly reduced size compared to conventional markers operating at lower frequency. As a result, the marker enables the reliable, quick, and efficient detection of retained instruments in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required. The small size further permits instruments to be tagged that could not be tagged with larger prior art markers. None of these beneficial attributes is afforded by any marker or tagged instrument constructed in accordance with the teachings of Fabian and Von Hoene et al., even if taken in combination.

It is thus respectfully submitted that even in combination, Fabian and Von Hoene et al. do not disclose or suggest the method of claim 14, the surgical implement of claim 22, or the system delineated by claim 26, as amended.

Accordingly, reconsideration of the rejection of claims 1-5, 12-16, 18, 19, and 22 under 35 USC 103(a) as being unpatentable over Fabian in view of VonHoene et al. is respectfully requested.

Claims 6, 7, and 11 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian and VonHoene et al. as applied to claims 1-5 above and further in view of US Patent No. 6,359,563 to Herzer, which provides a magneto-acoustic marker for electronic article surveillance having reduced size and high signal amplitude.



Inasmuch as claims 6 and 7 have been cancelled, the foregoing rejection will be discussed with respect to amended claim 11.

Like Fabian and VonHoene et al. as discussed above, Herzer does not disclose or suggest any marker configuration employing multiple resonator strips that are non-parallel. Accordingly, it is submitted that claim 11, which inherits the non-parallel feature from base claim 26 through intervening claim 9, is not obvious

Moreover, the reduction in size afforded by Herzer is attained by use of narrower magnetostrictive ribbon, e.g. ribbon 6 mm wide instead of the 12.7 mm wide ribbon that is said to be conventional. The resonant element in Herzer remains rectangular, with no recognition of shortening the long dimension of the marker, which is typically about 1.5 inches as required to maintain an operating frequency of about 55-60 kHz.

The Examiner has contended that that Herzer teaches use of a plurality of resonator pieces to allow the width of the marker to be reduced. As set forth above, Herzer does not cure the lack of disclosure or suggestion of the 70-300 kHz range in the combination of Fabian and VonHoene et al.,

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., and Herzer do not disclose or suggest the system delineated by applicants' claim 11, as amended.

Accordingly, reconsideration of the rejection of claims 6, 7, and 11 under 35 USC 103(a) as being unpatentable over Fabian and VonHoene et al. in further view of Herzer is respectfully requested.

Claims 8, 23, and 25 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian, VonHoene et al., and Herzer as applied to claims 6-7 above and

further in view of US Patent Publication No. 2002/0005783 to Irrizary et al., which provides a child monitoring device.

Inasmuch as the features of claims 8 and 23 have been subsumed in claims 26 and 22, respectively, and claim 25 has been cancelled, the following remarks will be addressed to claims 22 and 26, as amended.

As set forth above, even the combination of Fabian, VonHoene et al., and Herzer fails to suggest the 70-300 kHz range required by present claims 22 and 26. Irrizary et al. further fails to cure this deficiency.

The Examiner has acknowledged that the foregoing combination fails to teach a marker wherein a plurality of elongated strips is not disposed in parallel, and so has cited Irrizary et al. Applicants respectfully point out that Irrizary et al. fails to disclose or suggest any embodiment in which the plural, non-parallel strips are disposed in a single cavity. Instead, Irrizary et al. provides a marker that is a combination of two separate markers, with the respective resonant elements disposed in different cavities. Such a marker is inherently more complicated and difficult to construct, and entails use of more bias elements than needed in the present marker. As a result, it is submitted that there is no motivation for the substantial reconstruction that would be needed to reach the present claimed structure.

More specifically, applicants respectfully submit that the tag of Irrizary et al. comprises two magnetomechanical markers, having elongated axes that are perpendicular. Whereas each of the mechanical markers (e.g. markers 25 and 26 of tag 21 shown in Fig. 2) of Irrizary et al. separately includes a magnetomechanical elongated strip, applicant's marker includes a magnetomechanical element comprising a plurality of elongated strips. Present claim 26 recites in feature (a)(iii) a housing having a cavity enclosing the magnetomechanical element (a plurality of elongated strips, from feature (a)(i)) disposed in

the cavity in a non-parallel orientation with their centers coincident. Therefore, it is respectfully submitted Irrizary et al. does not disclose a marker wherein a magnetomechanical element comprises plural strips that collectively constitute a magnetomechanical element and are together enclosed in a cavity of a housing. Rather, the Irrizary et al. marker comprises multiple magnetomechanical elements that are enclosed in cavities in separate housings, even if the multiple markers are mechanically joined. Irrizary et al. further fails to disclose or suggest the particular resonant frequency range delineated by applicants, thereby failing to cure the aforementioned deficiency, even if all the applied references are taken in combination.

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., Herzer, and Irrizary et al. do not disclose or suggest the system delineated by applicant's system claim 26.

Accordingly, reconsideration of the rejection of claims 8, 23, and 25 under 35 USC 103(a) as being unpatentable over Fabian, VonHoene et al., and Herzer in view of Irrizary et al. is respectfully requested.

Claims 9 and 24 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian, VonHoene et al., Herzer, and Irrizary et al. and further in view of US Patent 6,407,676 to Tanji et al.

Tanji et al. provides a magnetostrictive resonator appointed to be embedded in a roadway for use in connection with a vehicle detection system.

The Examiner has acknowledged that the combination of Fabian, VonHoene et al., Herzer, and Irrizary et al. fails to disclose a configuration having magnetomechanical strips on either side of a bias magnet, but has contended that Tanji et al. teaches placing resonators

on both sides of the bias magnet to allow the marker to be made smaller. While Tanjii et al. and Irrizary et al. admittedly disclose markers having a plurality of elongated metal resonating elements, neither reference discloses or suggests any configuration in which the resonating elements are, in combination, in a single cavity, non-parallel, and have a bias element disposed between them, as delineated by base claims 22 and 26.

Applicants further submit that even in combination, Fabian, VonHoene et al., Herzer, Irrizary et al., and Tanji et al. fail to teach the claimed frequency range of about 70 to 300 kHz, as delineated by claims 26 and 22, on which claims 9 and 24 respectively depend. Accordingly, it is submitted that claims 9 and 24 are patentable for at least the same reasons as claims 26 and 22, as set forth hereinabove.

Moreover, as set forth in conjunction with the rejection of claims 6, 7, and 11 over Fabian, VonHoene et al., and Herzer, the use of plural bias strips in the manner of either Herzer, Irrizary et al., or Tanji et al. at best permits a marker to be narrowed in its width dimension. Such narrowing does not affect the required length dimension, which must still be maintained because of the selection of the particular resonant frequency employed by conventional systems, e.g. about 60 kHz. Especially in embodiments in which parallel strips are used, the length dimension is necessarily dominant. See, e.g., Von Hoene et al. at col. 4, lines 5-7. Nothing in any of the cited references addresses this limitation or suggests the desirability of a medical implement detection system employing shorter markers. None the aforementioned benefits of such a system for surgical instrument detection is afforded by any marker or system constructed in accordance with the combined teachings of Fabian, VonHoene et al., Herzer, Irrizary et al., and Tanji et al.

Accordingly, reconsideration of the rejection of claims 9 and 24 under 35 USC 103(a) as being unpatentable over Fabian, VonHoene et al., Herzer, and Irrizary et al. and further in view of Tanji et al. is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application has been placed in allowable condition. Reconsideration of the rejection and allowance of pending claims 9, 11-14, 22, 24, and 26, as amended, are, therefore, earnestly solicited.

Respectfully submitted,

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